3. 510(K) SUMMARY

FEB - 2 2010

Applicant - Manufacturer Name and Address
Micro Therapeutics dba ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618
Establishment Registration No. 2029214

Date: January 08, 2010

Contact Information
Laura Heaton
Senior Regulatory Affairs Specialist
Main: (949) 837-3700
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Trade Names
HyperForm™ Occlusion Balloon Catheter
HyperGlide™ Occlusion Balloon Catheter

Device Classification & Common Name

Product Code:	MJN, 21CFR Part 870.4450
Classification:	Class II
Classification Name:	Catheter, Intravascular Occluding, Temporary
Common Name:	Occlusion Balloon Catheter

Predicate Devices - 510(k) References

HyperGlide™ Occlusion Balloon Catheter	K092495
HyperGlide™ and HyperForm™ Occlusion Balloon Catheters	K091458
HyperGlide™ Occlusion Balloon Catheter	K090728
HyperGlide™ Occlusion Balloon Catheter	K021066
HyperForm™ Occlusion Balloon Catheter	K011656

Description of the Device Subject to Premarket Notification

The Occlusion Balloon Catheter is a single lumen balloon catheter that requires the insertion of the 0.010" guidewire to occlude the central lumen to allow inflation of the balloon. When the distal 10 cm platinum coil tip of the guidewire is advanced to or past the catheter tip, it occludes the inflation holes allowing the balloon to inflate through catheter sideholes. The Occlusion Balloon Catheters are marketed as the HyperForm™ and HyperGlide™ Occlusion Balloon Systems which include a guidewire.

Indications for Use

The Occlusion Balloon Catheter is designed for the use in the blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. The Occlusion Balloon Catheter offers a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow.

Performance Data

The Occlusion Balloon Catheter devices have not changed; therefore there is no performance data included in this submission. The Instructions for Use have been revised to remove the pediatric and neonatal contraindication.

Substantial Equivalence

The devices have not changed and no new risks have been identified. The indications for use demonstrate the ev3 Occlusion Balloon Catheters are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB - 2 2010

EV3 Neurovascular
c/o Laura Heaton
Senior Regulatory Affairs Specialist
9775 Toledo Way
Irvine, CA 92618

Re: K100063
Trade/Device Name:
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II (two)
Product Code: MJN
Dated: January 8, 2010
Received: January 15, 2010

Dear Ms. Heaton:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100063

2. STATEMENT OF INDICATIONS FOR USE

Indications for Use

510(k) Number (if known):

Device Name: HyperForm™ Occlusion Balloon Catheters

Indications for Use: The HyperForm™ Occlusion Balloon Catheters are indicated for the use in blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. These catheters offer (1) a vessel selective technique of temporary vascular occlusion, which is useful in selectively stopping or controlling blood flow, and (2) for balloon-assisted embolization of intracranial aneurysms.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K100063